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(54) **POSTERIOR INTERVERTEBRAL DISC
INSERTER AND EXPANSION TECHNIQUES**

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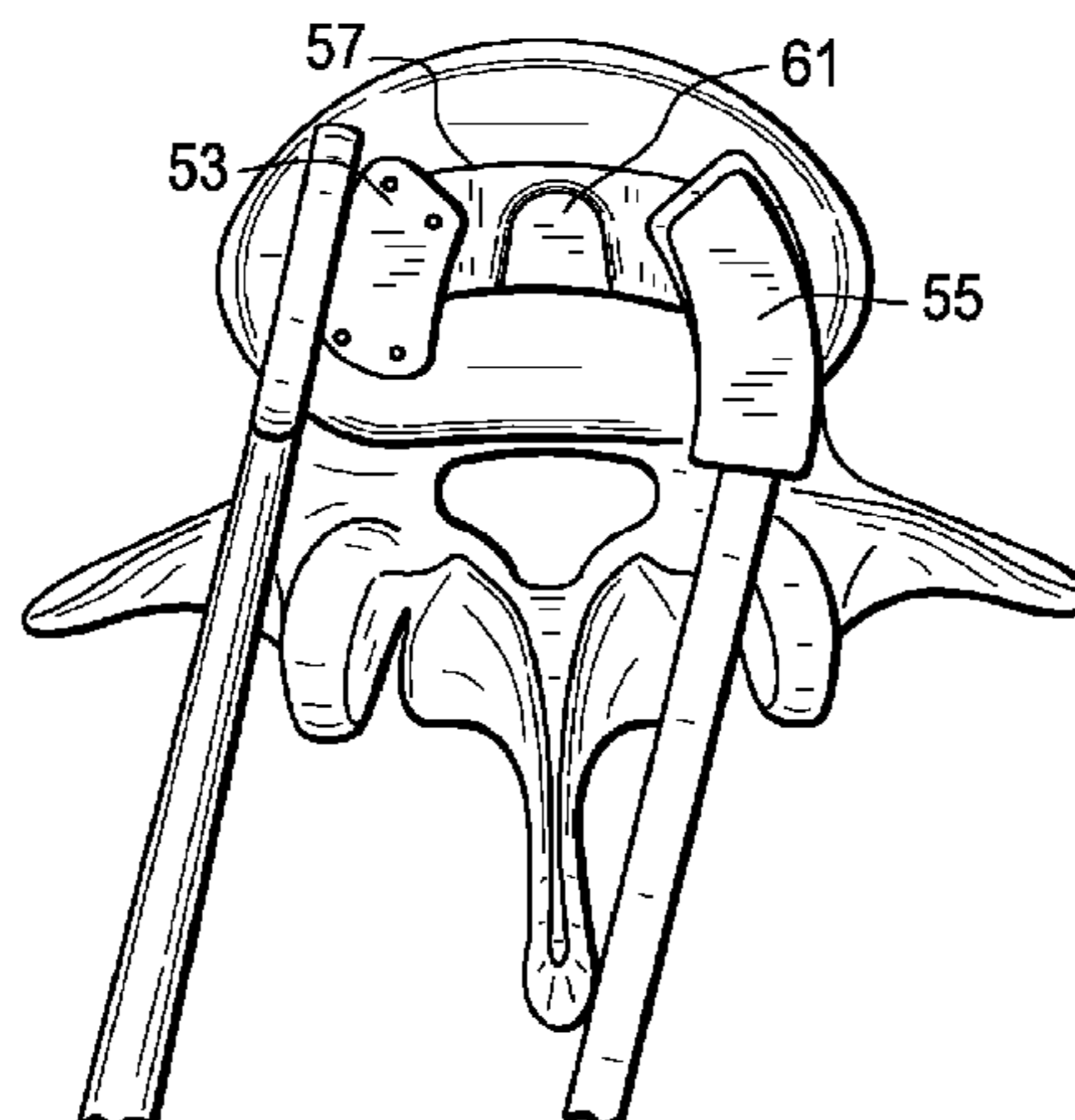
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(57) **ABSTRACT**
Insertion and expansion devices for use in inserting motion
discs, and associated methods of use.

39 Claims, 7 Drawing Sheets



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FIG. 1

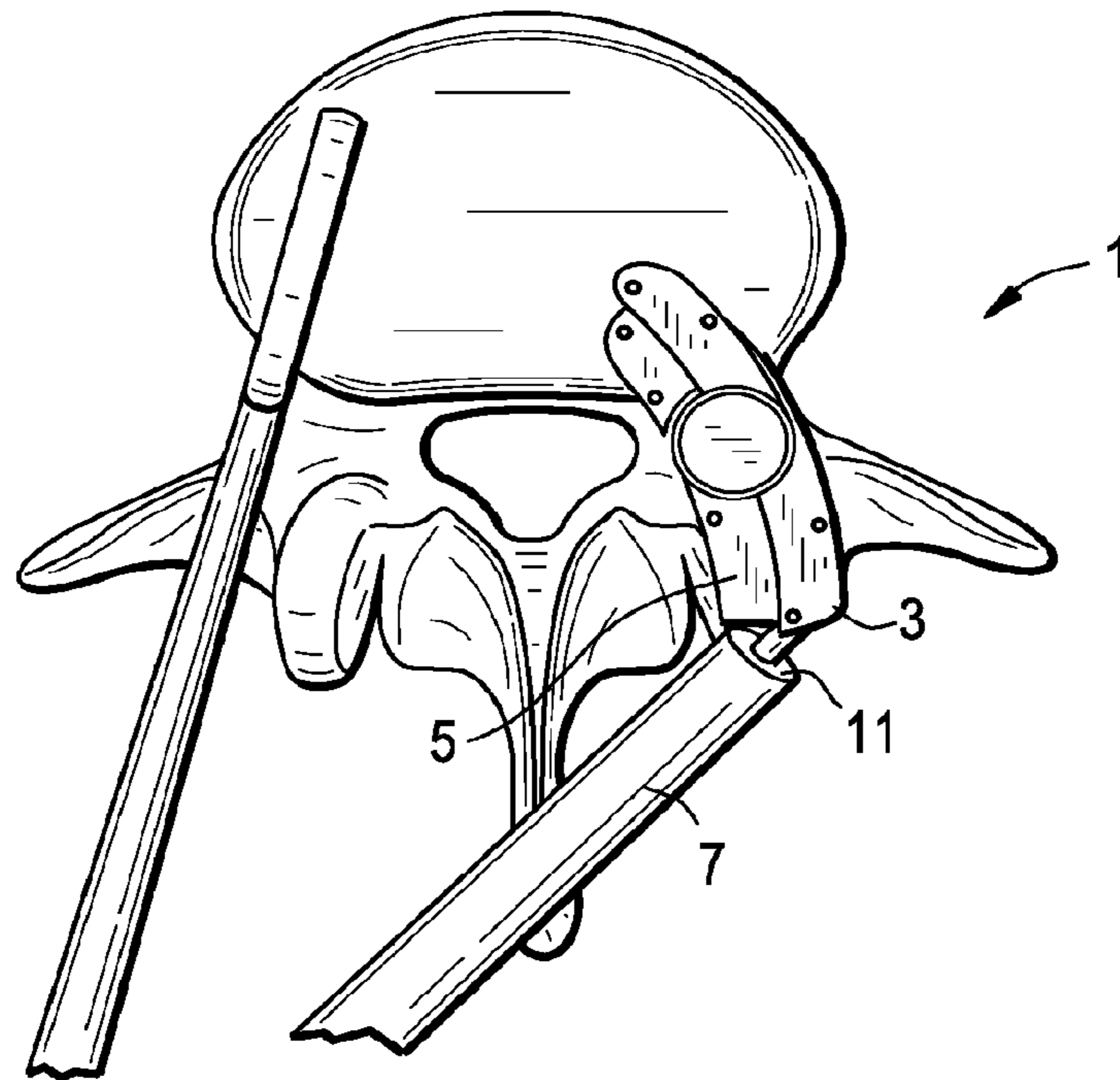


FIG. 2

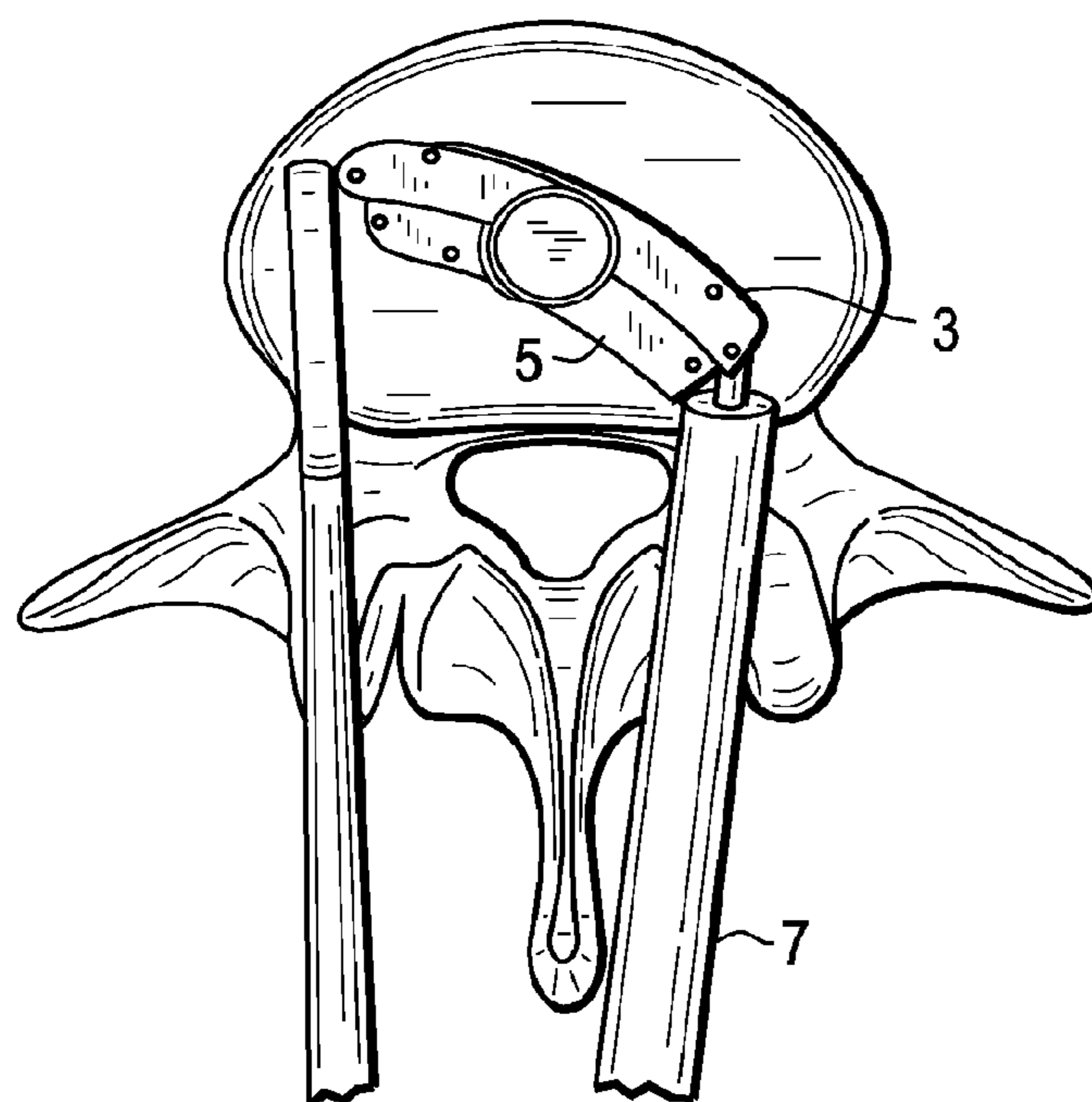


FIG. 3

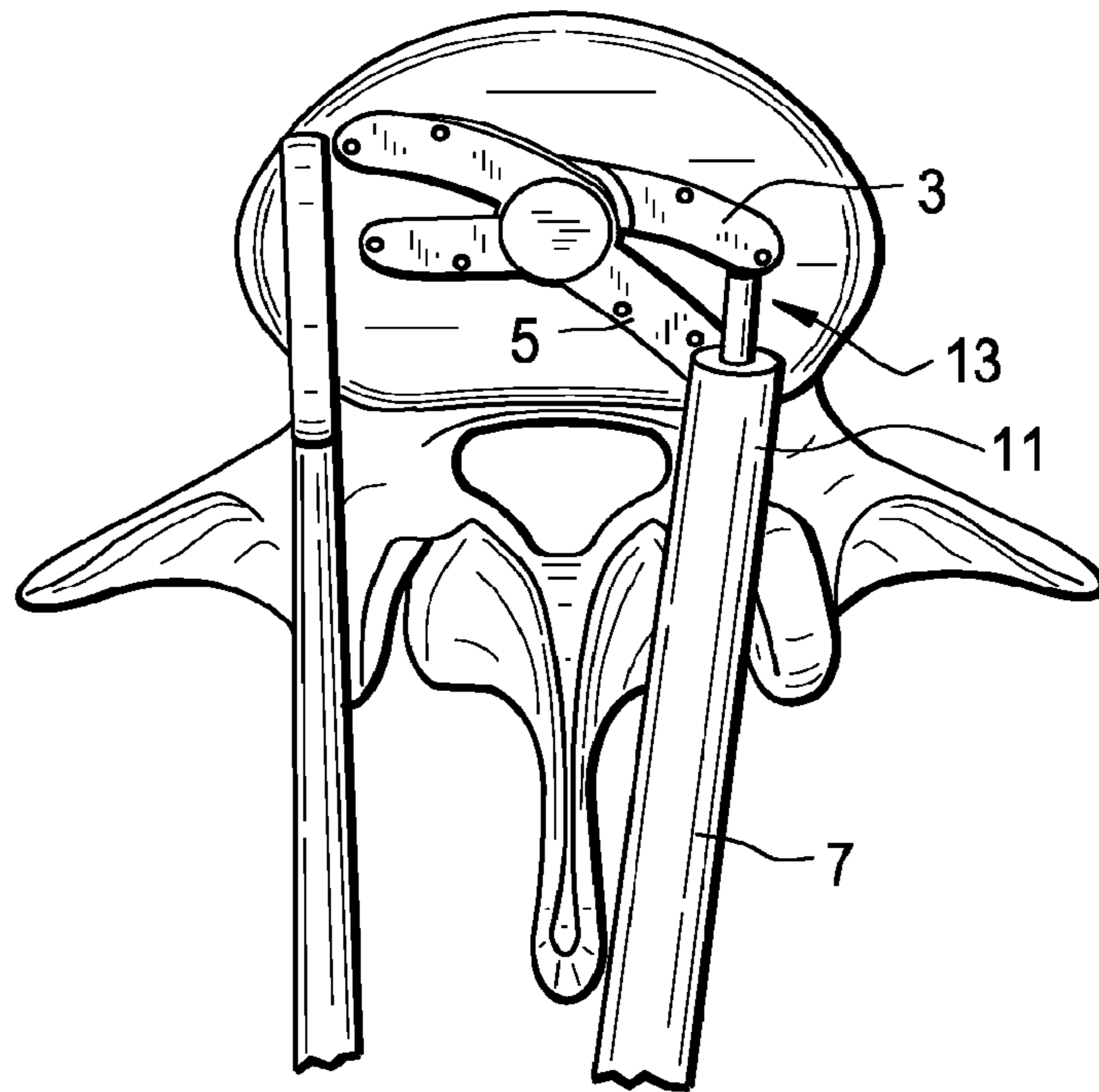


FIG. 4

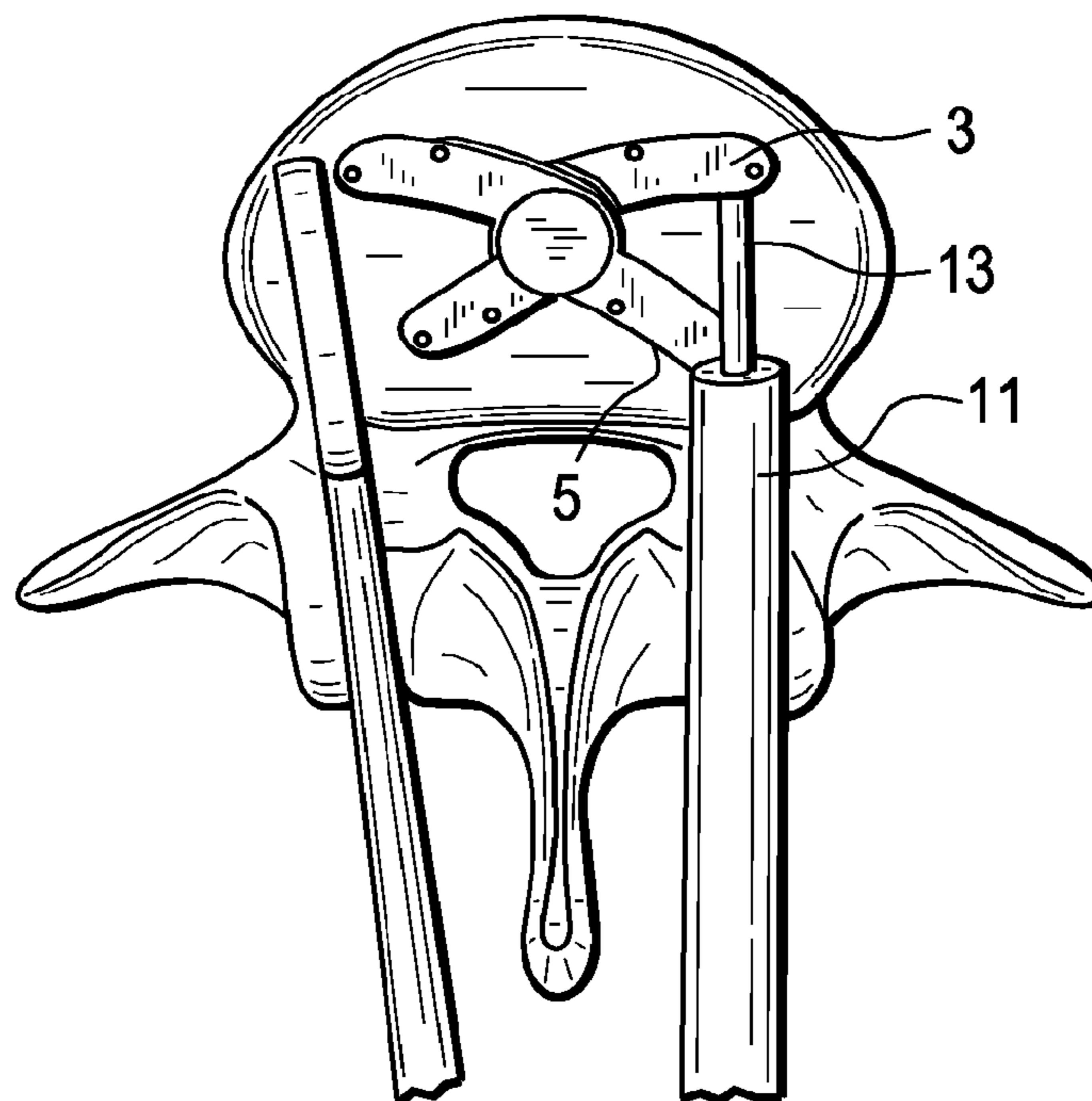


FIG. 5

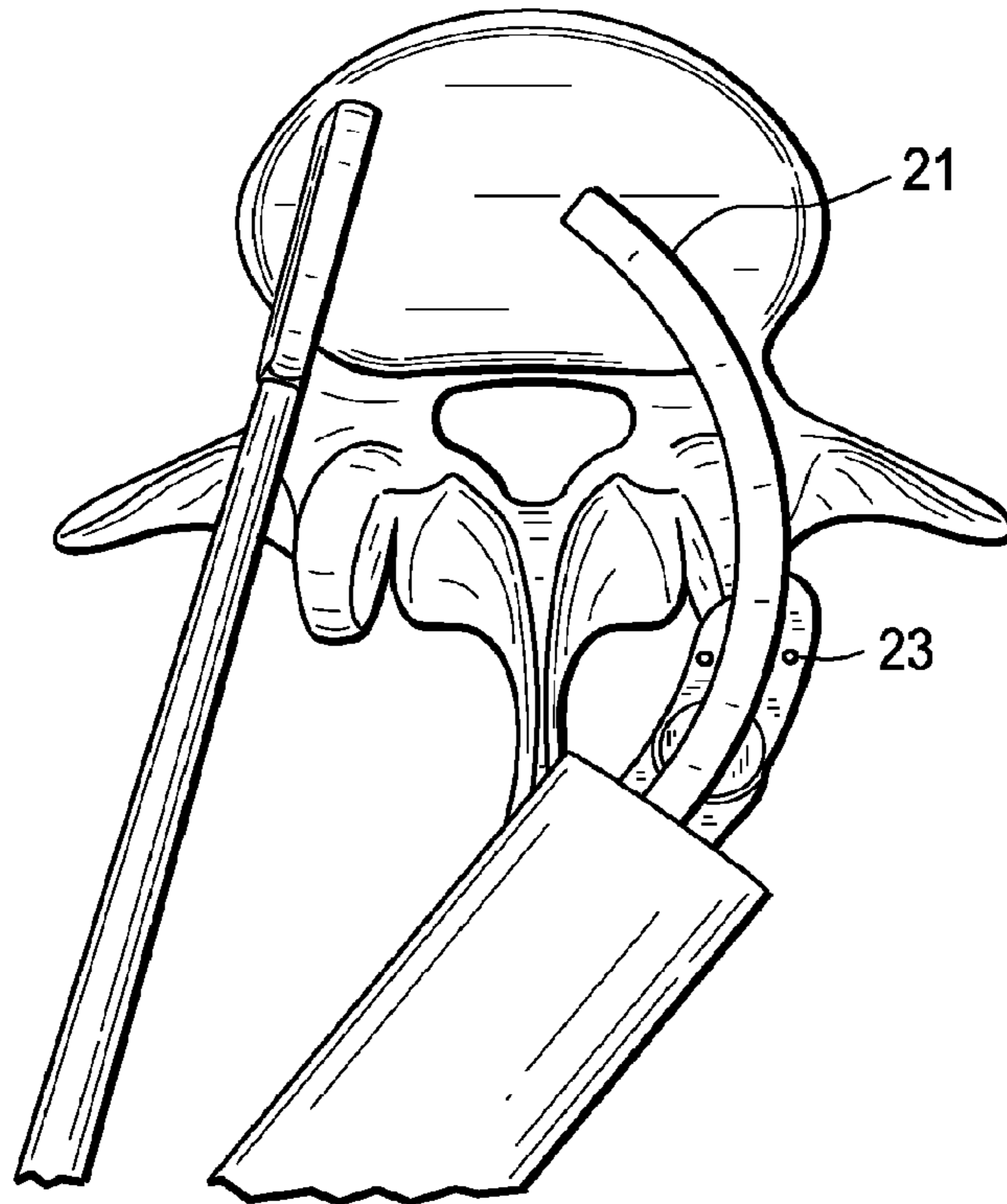


FIG. 6

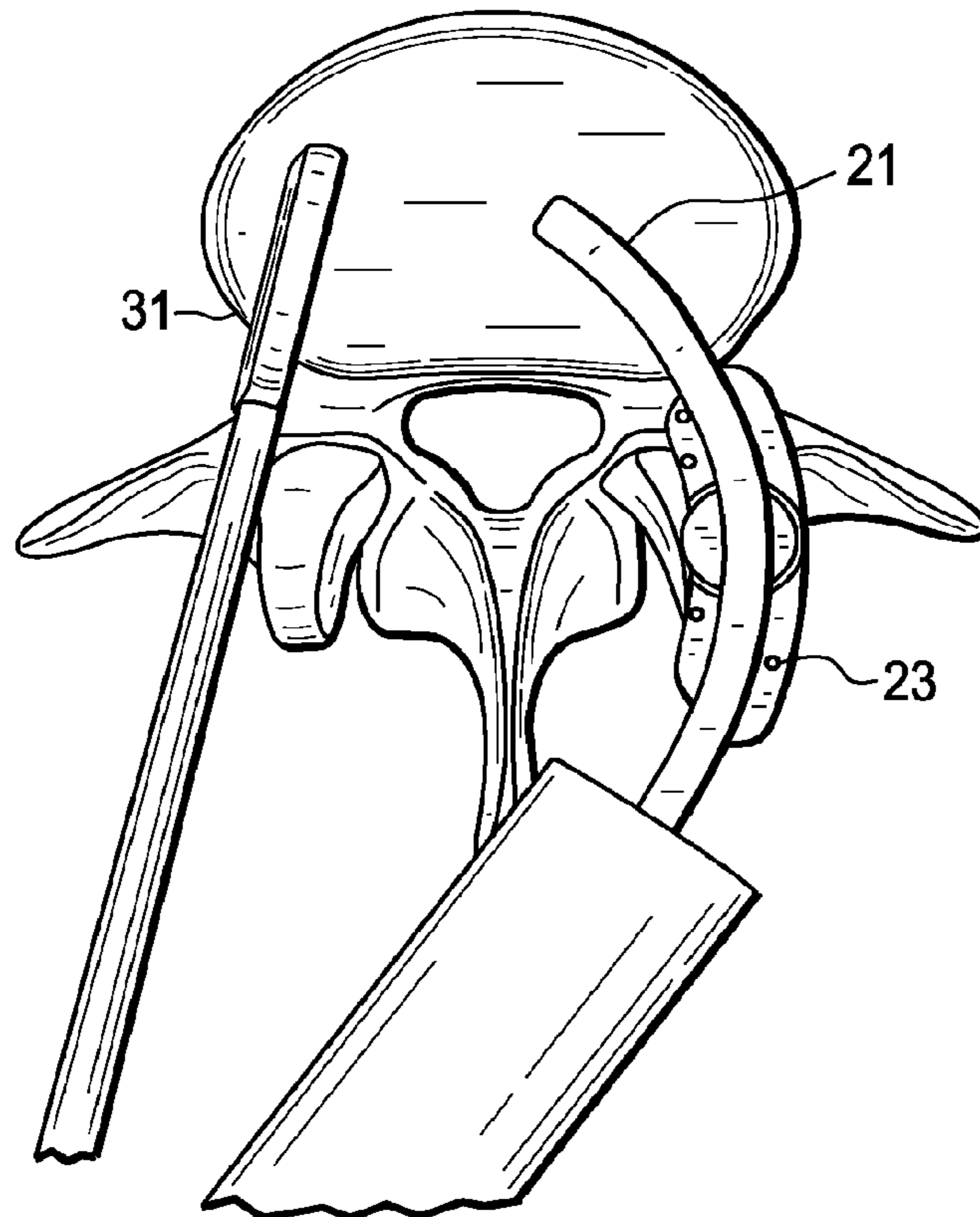


FIG. 7

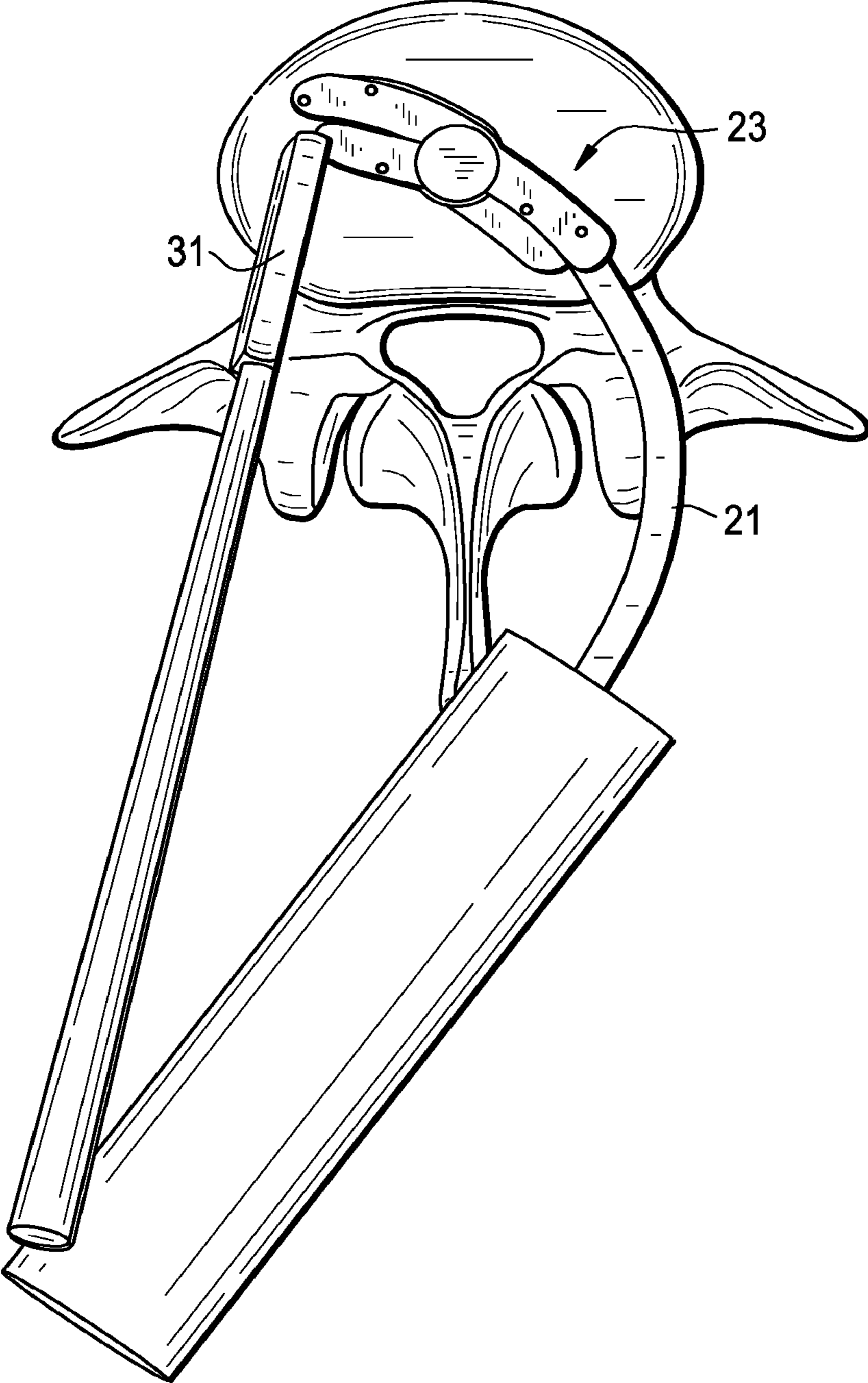


FIG. 8

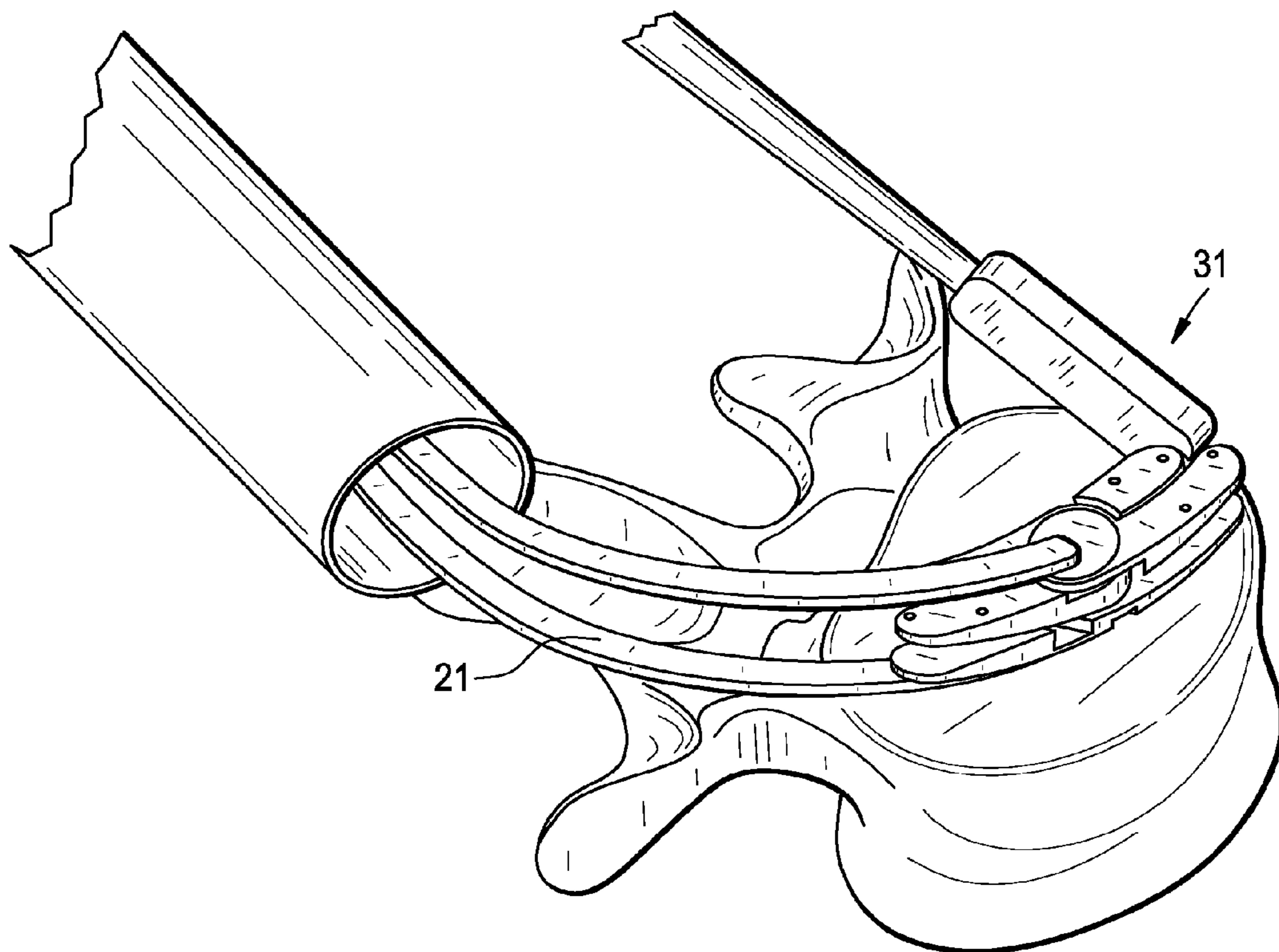


FIG. 9

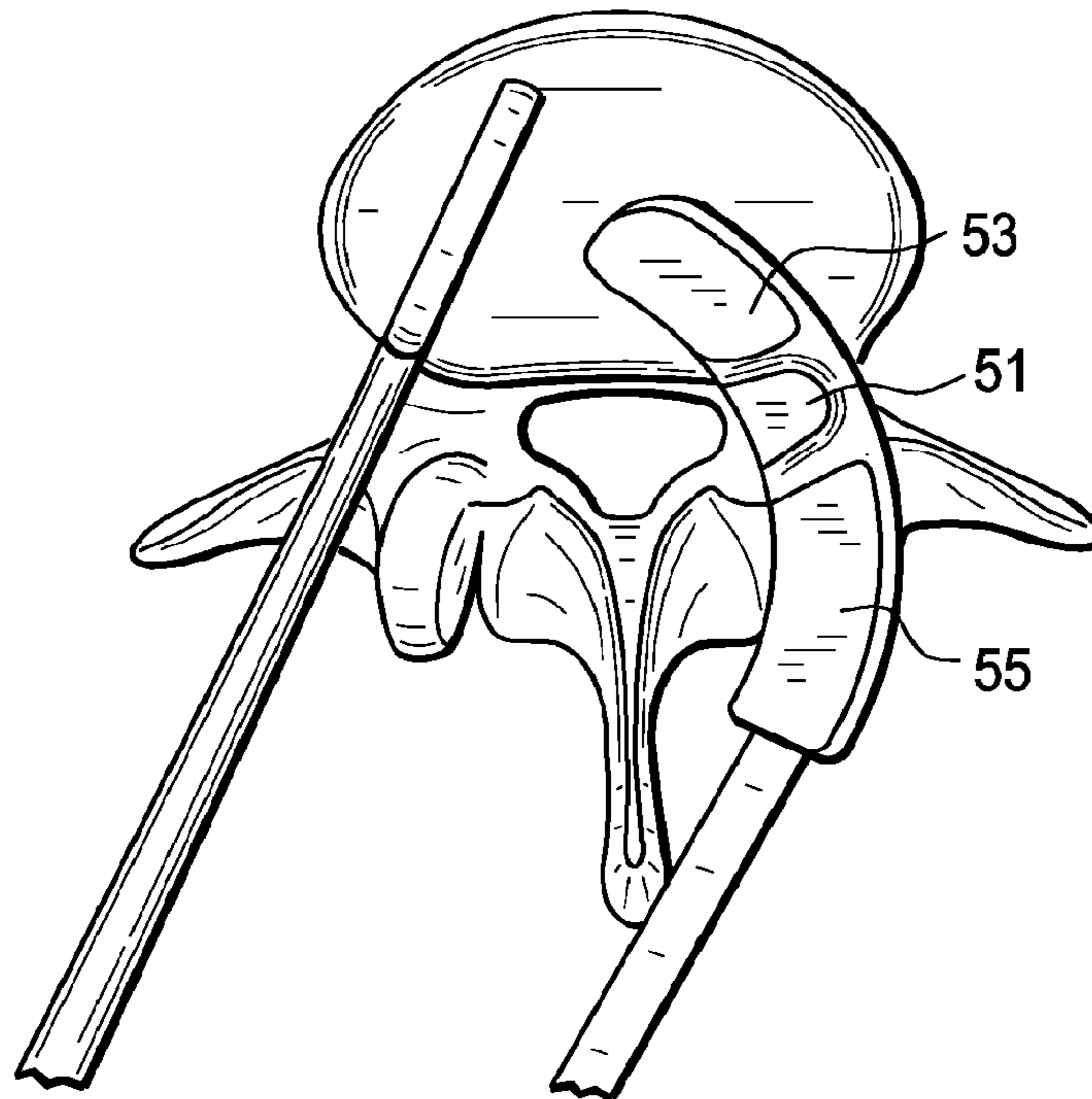


FIG. 10

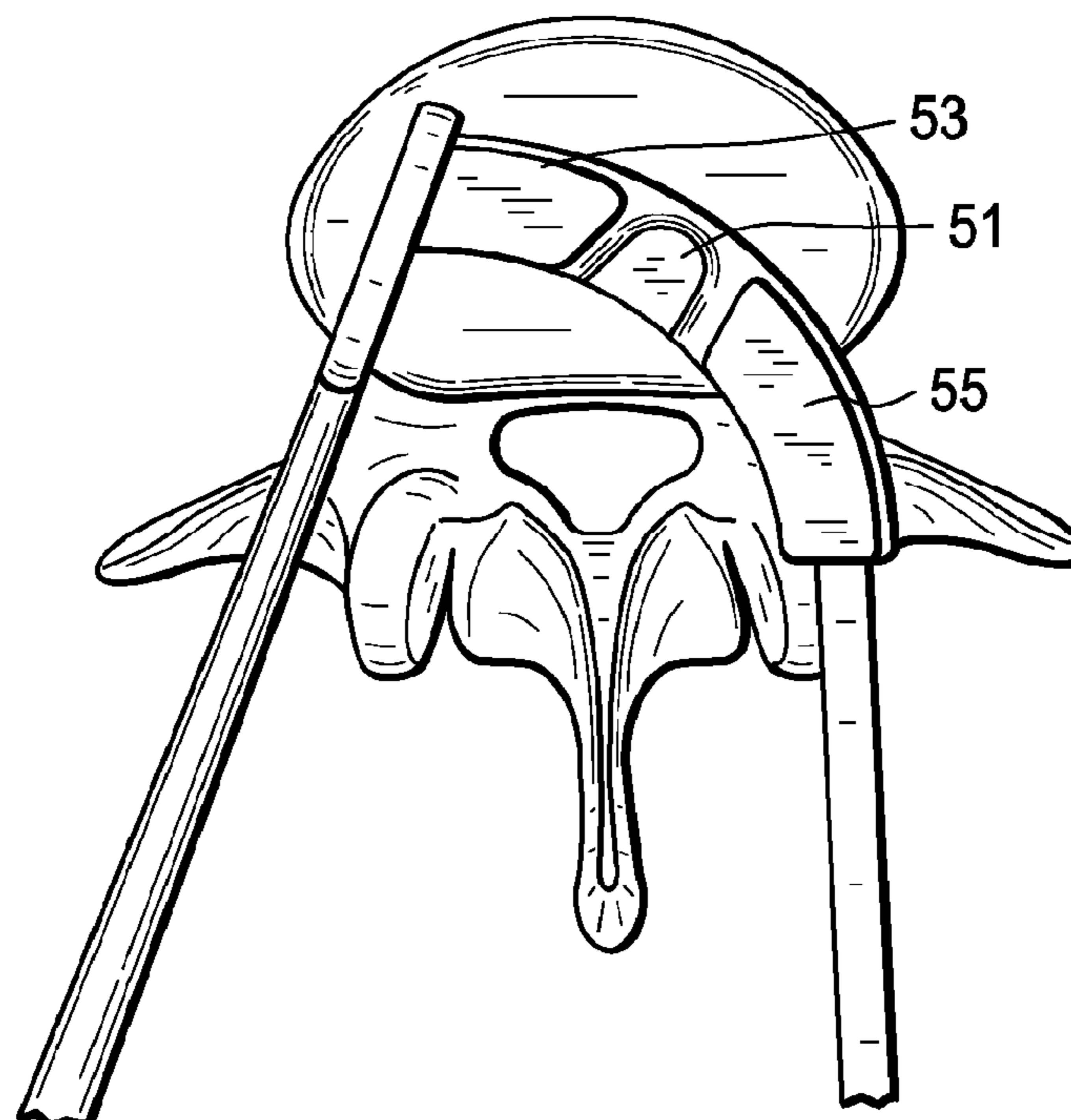


FIG. 11

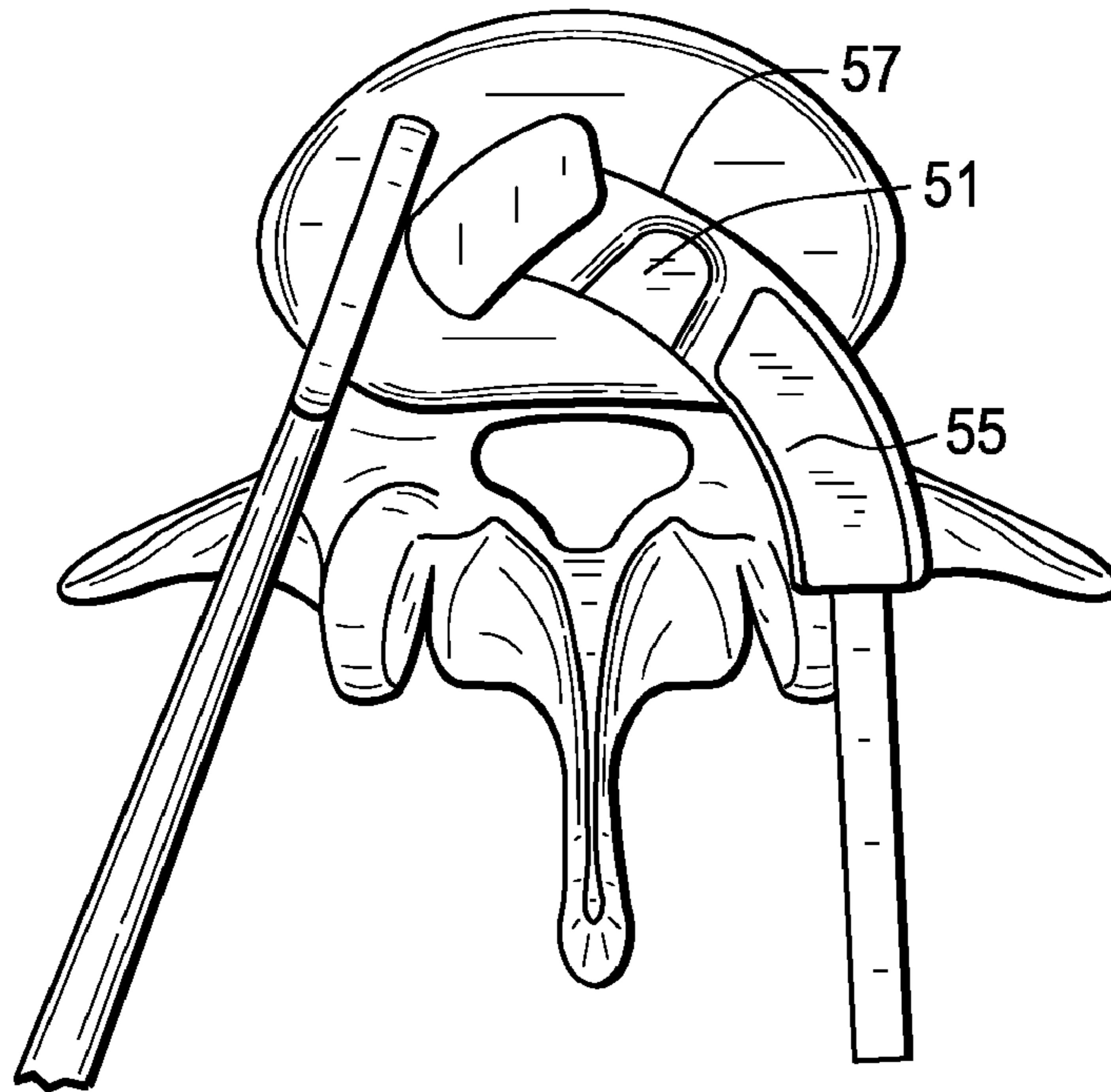
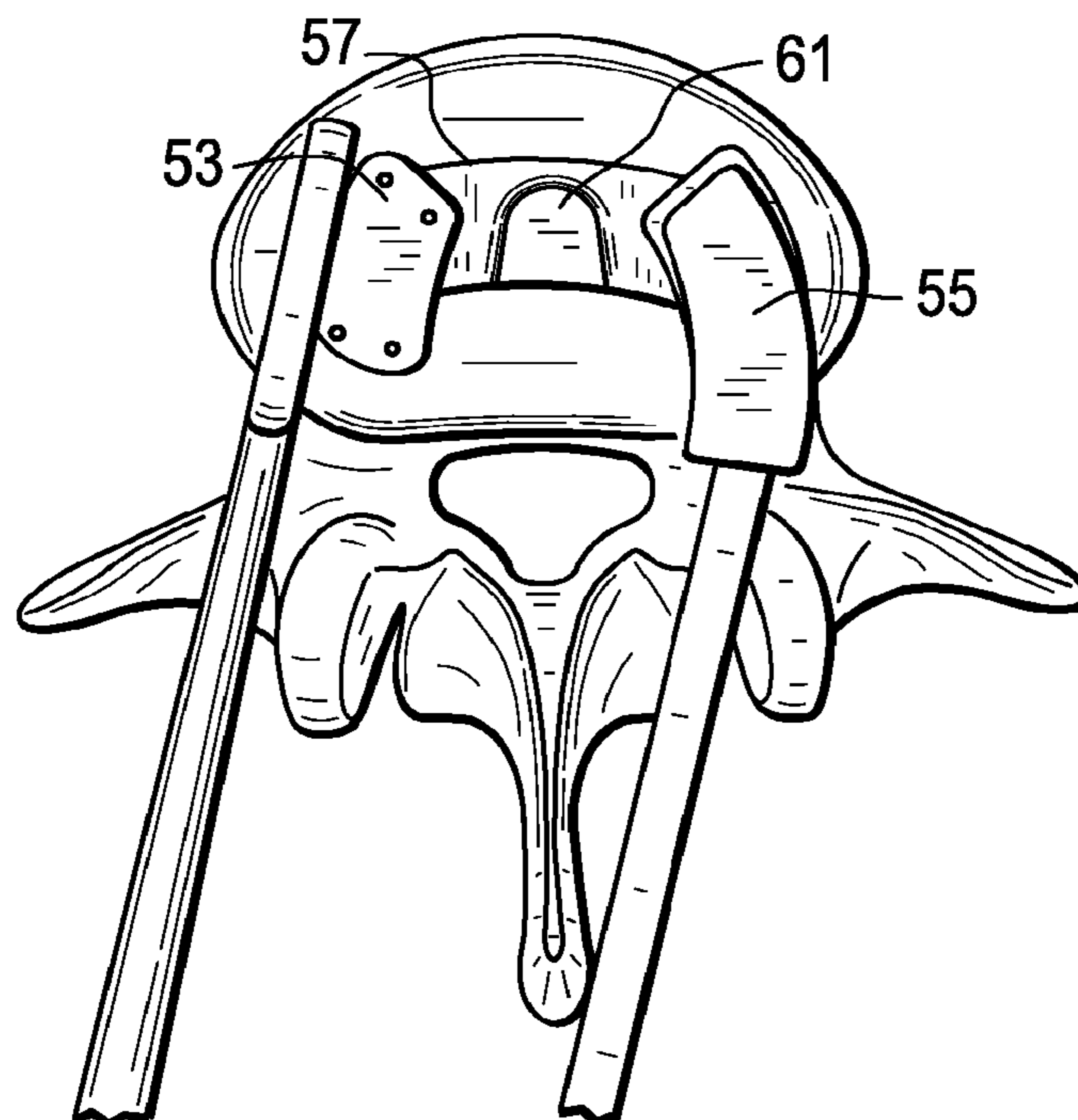


FIG. 12



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**POSTERIOR INTERVERTEBRAL DISC
INSERTER AND EXPANSION TECHNIQUES**

CROSS-REFERENCE TO RELATED
APPLICATIONS

This is a continuation application of U.S. patent application Ser. No. 12/055,779 filed Mar. 26, 2008, the disclosure of which is hereby incorporated by reference as if set forth in its entirety herein.

BACKGROUND OF THE INVENTION

The leading cause of lower back pain arises from rupture or degeneration of lumbar intervertebral discs. Pain in the lower extremities is caused by the compression of spinal nerve roots by a bulging disc, while lower back pain is caused by collapse of the disc and by the adverse effects of articulation weight through a damaged, unstable vertebral joint. One proposed method of managing these problems is to remove the problematic disc and replace it with a prosthetic disc that allows for the natural motion between the adjacent vertebrae (“a motion disc”).

There are many types of motion disc inserters disclosed in the prior art. These devices generally hold the inferior and superior endplates of the motion disc for “line of site” insertion. Positive stops and measurement devices are also employed on these inserters to determine the appropriate depth of implant placement.

PCT Published Patent Application WO 2006-058281 (“Glenn”) discloses a spinal implant to be inserted between two vertebra to support and stabilize adjacent vertebra and allow for physiological motion. The invention includes an implantable device to support the vertebrae, and a minimally invasive method for inserting and deploying the device within the intervertebral space.

SUMMARY OF THE INVENTION

The present invention relates to insertion and expansion devices for use in inserting intervertebral motion discs, and associated methods of use. They are grouped into two separate devices and techniques as follows:

In a first embodiment, the inserter has a longitudinal handle having a distal pair of holders for holding a proximal end of a pivoting motion disc, wherein one of the holders is axially deployable within the handle. The pair of holders secure the proximal legs of the implant for insertion into the disc space. This assembly utilizes an implant first methodology, wherein this assembly is inserted into the disc space in an orientation wherein the implant is on the leading end of the assembly. Once the motion disc is placed into the disc space, a secondary deployer associated with the handle is activated to axially move one of the holders, thereby moving one of the legs relative to the other leg and thereby changing the disc device footprint (e.g., pivoting one of the legs). Several expansion mechanisms can be used to expand the legs of the implant.

The approach used in conjunction with this first embodiment may include one or more annular locations. For example, in some embodiments, the approach is ipsilateral. In some embodiments, the approach is contralateral, or both. In some embodiments, the first embodiment of the present invention produces an X-shaped artificial intervertebral disc in its expanded condition. However, other expanded motion disc geometries, such as an H-shape artificial intervertebral disc in its expanded condition, are also contemplated.

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Therefore, in accordance with the present invention, there is provided a method of inserting a curvilinear motion disc having a first and second legs connected by a pivot, each leg having an endportion, the method comprising the steps of:

- a) providing the motion disc in a collapsed position,
- b) providing a motion disc inserter comprising a handle having a longitudinal axis and a first end having first holder and a deployer, the deployer being axially moveable along the axis of the handle,
- c) attaching the first endportion of the motion disc to the first holder,
- d) contacting the second endportion of the motion disc to the deployer,
- e) arcuately inserting the motion disc into the disc space in the collapsed condition, and
- f) axially moving the deployer to move the second leg and to expand the motion disc into an open condition.

Therefore, in accordance with the present invention, there is provided an assembly for inserting a curvilinear motion disc into a disc space, the assembly comprising:

- a) a curvilinear motion disc having first and second pivoting legs, each leg having an endportion, wherein the first and second leg endportions are in a first collapsed position, and wherein the first and second leg endportions are in a second expanded position, and
- b) an inserter comprising a handle having a longitudinal axis and a first end having a first holder and a deployer, the deployer being axially moveable along the axis of the rod, wherein the first endportion of the motion disc is attached to the first holder, and wherein the second endportion of the motion disc is attached to the deployer.

In a second embodiment, the insertion instrument possesses an insertion track. The insertion track instrument is inserted into the disc space by itself and creates an annular shield for the motion disc implant (thereby protecting the disc). It also provides a guide or track for the subsequently-placed motion disc implant insertion and placement to follow during insertion. Lastly, the guide/track facilitates expansion of the motion disc footprint by holding the central axis pivot point.

Therefore, in accordance with the present invention, there is provided a method of inserting a curvilinear motion disc having first and second endportions, the method comprising the steps of:

- a) providing the motion disc in a collapsed position wherein the first and second endportions are close together,
- b) inserting into a disc space a distal portion of a motion disc inserter comprising a tubular proximal portion and a curved distal portion comprising upper and lower rails,
- c) advancing the motion disc in the collapsed condition through the motion disc inserter to insert the motion disc into the disc space and rotate the motion disc, and
- d) expanding the motion disc into an open condition in the disc space.

The methods of the present invention differ from those of the prior art because the present methods employ non-linear insertion techniques with instruments having deployment features that expand or change the footprint of an artificial intervertebral disc implant.

Some embodiments of this invention differs from prior art because it employs an expansion means to change location and footprint of the artificial disc, wherein the expansion means is independent of the insertion method.

This invention differs from the prior art because it does not use screw attachment to couple the inserter to the implant.

DESCRIPTION OF THE FIGURES

FIG. 1 discloses inserting a first motion disc/inserter assembly into the disc space, wherein the motion disc is in a collapsed condition.

FIG. 2 discloses advancing the motion disc of FIG. 1 further into the disc space to rotate the motion disc.

FIG. 3 discloses the initial actuation of the deployer to expand the motion disc to a partially expanded condition.

FIG. 4 discloses the complete actuation of the deployer to expand the motion disc to a final expanded condition.

FIG. 5 discloses advancing a motion disc up a linear proximal portion of a second motion inserter, wherein the motion disc is in a collapsed condition.

FIG. 6 discloses further advancing the motion disc of FIG. 5 through a curved intermediate portion of the inserter to rotate the motion disc.

FIG. 7 discloses further advancing the motion disc of FIG. 6 through a curved distal portion of the inserter to insert the motion disc into the disc space.

FIG. 8 discloses the final placement of the motion disc of the FIG. 7 in the disc space.

FIG. 9 discloses advancing an H-type motion disc up a linear proximal portion of a second motion inserter, wherein the motion disc is in a collapsed condition.

FIG. 10 discloses further advancing the motion disc of FIG. 9 through a curved distal portion of the inserter to rotate the motion disc and insert the motion disc into the disc space.

FIG. 11 discloses the initial actuation of the motion disc of FIG. 10 to expand a first leg of the motion disc.

FIG. 12 discloses the final actuation of the motion disc of FIG. 11 to expand a second leg of the motion disc.

DETAILED DESCRIPTION

Now referring to FIGS. 1-4, there is provided a method of inserting a motion disc having a first and second legs connected by a pivot, each leg having an endportion, the method comprising the steps of:

- a) providing the motion disc **1** in a collapsed position wherein the first **3** and second **5** leg endportions are close together,
- b) providing a motion disc inserter **7** comprising a handle having a longitudinal axis and a first end **11** having first **13** and second holders, the deployer being axially moveable along the axis of the handle,
- c) attaching the first endportion of the motion disc to the first holder,
- d) attaching the second endportion of the motion disc to the deployer,
- e) inserting the motion disc into the disc space in the collapsed condition, and
- f) axially moving the deployer to move the second leg and to expand the motion disc into an open condition.

In particular, and now referring to FIG. 1, the motion disc inserter secures the proximal portion of the motion disc implant for insertion into the disc space by grasping the top and bottom aspects of the proximal portion of the intradiscal device. Now referring to FIG. 2, the implant is inserted into its desired location in the disc space.

Now referring to FIG. 3, with the implant in its desired location, the deployment component of the inserter is acti-

vated to expand or adjust the implant shape for improved vertebra body contact and balanced load transfer. In particular, the expansion component of the inserter is activated to move the deployer axially and thereby pivot one of the legs of the implant shape. This produces expansion of the implant, improved vertebra body contact and a more balanced load transfer. Means for the axial movement of the deployer (and thereby the second leg) include: a) a rod that is slideably movable within a tube, b) a threaded rod that is threadably movable within a threaded tube, and c) a notched rod that is capable of ratcheted actuation.

FIG. 4 shows the motion disc in its expanded condition after it has been expanded by activation of the inserter.

The extent to which the deployer can be axially moved can be monitored via depth markings. In some embodiments, the depth markings are placed on the deployer. In some embodiments, the depth markings are placed on the insertion handle.

Although the inserter/deployer is shown in FIGS. 1-4 as being utilized in a posterior approach, it can be also used for other angles of approach, including lateral, anterior, and postero/lateral approaches.

The implant used in conjunction with the first embodiment can be of varying shape and configurations. Typically, it has at least one pivoting leg. In some embodiments, it has a pair of pivoting legs. An "X shaped" implant is shown in FIGS. 1-4. The X-shape can have multiple layers wherein inferior and superior layers are held or deployed individually or simultaneously. Other disc implant geometries can utilize the inserter holder/deployer of the first embodiment to insert an implant and change the footprint via disclosed the deployment means. An example of an alternate geometry is a "T"-, "Y"- or "H"-shaped implant.

In some embodiments, the handle portion of the present invention comprises a tube within which the deployer is contained. In some embodiments, the first holder is fixedly attached to the distal end portion of the tube. In other embodiments, the handle portion of the present invention comprises a solid rod, and the holders are attached to the outer surface of the rod.

The insertion track of the second embodiment of the present invention is curvilinear and has a blade, semi-tubular or tubular construction, thereby allowing negotiation of bony or soft tissues without damaging those tissues. This track provides a fixed route for insertion and rotation of the motion disc. In some embodiments, it has a substantially linear proximal portion and a curved distal portion. In some embodiments, the linear proximal portion is tubular. In some embodiments, the curved distal portion can also be tubular. However, in other embodiments, the curved distal portion can comprise upper and lower rails that mate with the upper and lower aspects of the motion disc. The insertion track also allows insertion of the motion disc via a trajectory more comparable to that of the inner wall of the annulus fibrosus, as compared to "line of site" linear insertion techniques. This compatible trajectory has the advantage of intruding upon less of the annulus fibrosus during device insertion. In use, the track is inserted into the disc space prior to insertion of the motion disc. Doing so creates an annular shield around the implant so that the implant can be safely inserted into the disc space. The curved feature of the insertion track also creates a guide for turning the device during device placement. It may also provide a method of changing the device footprint by virtue of a guiding pusher for expansion of shape.

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Now referring to FIG. 5, there is provided an insertion track 21 of the present invention following its insertion into the disc space along the annular inner wall.

Now referring to FIG. 6, a motion disc implant 23 is shown advancing along this insertion track to enter the disc space. Now referring to FIG. 7, the implant is advanced along the track until its final desired central placement is obtained. The placement depth can be limited by a positive stop(s) along the insertion track (proximal tip stop (not shown)). The depth to which the implant is inserted into the disc space can be monitored via depth markings provided on the track and referencing off an adjacent vertebral body.

Several methods of advancing the device along the insertion track can be carried out in accordance with the present invention. These methods include using a pusher instrument that holds and pushes the proximal end of the implant to advance it distally along the track. Another possible method may use a puller comprising a cable wrapped around a pulley located at the distal tip of the track, wherein one free end of the cable is connected to the implant and the other free end extends out of the proximal tubular portion of the insertion track. In this case, providing a tensile or pull force on the cable moves the device distally along the track and into the disc space.

Various methods of deployment can be used to change the device footprint once the motion disc is placed within the disc space. In one embodiment, the method includes temporarily attaching interconnecting features that connect the insertion track to the implant, and withdrawing the insertion track from the disc space, thereby changing the footprint of the implant via the insertion track extraction forces. In a second embodiment, and now referring to FIG. 8, the method includes placing on the contra-lateral side of the disc space an instrument to create an advancement stop. Instrument 31 has a puller mechanism, activating the puller mechanism and pulling or pushing the motion disc into position. In alternate embodiments, the contralateral puller or pusher mechanism may be actuated to change the footprint configuration of the motion disc.

In some embodiments, the insertion track can be directly connected to the implant, which provides the advantage of controlled trajectory and final position. In other embodiments, the insertion track can be connected to a holder/spacer that is attached to the implant and the insertion track, which provides the advantage of determining the angle of approach and entry for the puller/pusher mechanism.

The implant used in conjunction with the second embodiment can be of varying shape and configurations. Typically, it has at least one pivoting leg. In some embodiments, it has a pair of pivoting legs. An X-shaped implant is shown in FIGS. 5-8. The X-shape can have multiple layers, wherein various inferior and superior layers are held and/or deployed individually or simultaneously. Other disc implant geometries can exploit the insertion track to insert an implant and change the footprint via disclosed deployment means. In some embodiments, the alternate implant geometry comprises a "T"-, "Y"- or "H"-shaped implant.

FIGS. 9-12 disclose the insertion and actuation of an H-type motion disc using the insertion track inserter of the present invention. This motion disc has a central body 51 having first 53 and second 55 endportions, wherein a first leg 57 is pivotally attached to the first endportion at a first pivot, and wherein a second leg 61 is pivotally attached to the second endportion at a second pivot. Upon expansion, each of the legs of this device pivots to an orientation perpendicular to the longitudinal axis of the central body, and the device takes on an "H" shape.

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Now referring to FIG. 9, an H-type motion disc in a collapsed condition is advanced up a linear portion of the insertion track inserter. Now referring to FIG. 10, the H-type motion disc is further advanced through a curved portion of the insertion track inserter to rotate the motion disc and insert the motion disc into the disc space. Now referring to FIG. 11, initial actuation of the motion disc causes the pivoting of first leg of the motion disc and initial expansion of the motion disc. Now referring to FIG. 12, final actuation of the motion disc causes pivoting of the second leg of the motion disc and complete expansion of the motion disc.

Irrespective of the embodiment selected, if desired, an optional guide 101 (shown in FIG. 8) can be utilized during insertion and deployment to assist the surgeon in any one of disc space distraction, implant positioning, implant expansion, and/or verifying implant placement. This guide is typically placed on a contralateral side of the disc space. When the guide is used as a distractor, it typically has a transverse cross-section having a height and a width, wherein the width is greater than the height. The distractor is inserted into the disc space contralaterally so that its height dimension bears against the endplates. Prior to insertion of the motion disc, the distractor is rotated 90 degrees so that its width dimension now bears against the endplates, thereby increasing the height of the disc space.

Irrespective of the embodiment selected, in some embodiments, the inserter/deployer (as shown in FIGS. 1-4) or the insertion track (as shown in FIGS. 5-8) is used in a freehand manner. However, in other embodiments, the inserter/insertion track further comprises a docking means to dock onto or reference off nearby stable landmarks such as a vertebral body edge or a pedicle screw. Docking off of these locations provides for enhanced surgical stability and control.

Irrespective of the embodiment selected, intraoperative imaging techniques (including fluoroscopy) can be used to assist in or verify placement and deployment of the inserter and/or motion disc. Although the primary surgical approach shown is posterior or posterior/lateral, other approaches can be utilized.

Although the inserter/deployer and insertion track inserters are shown as being utilized posteriorly, they can be also used for other angles of approach including lateral, anterior, and posterior/lateral approaches.

We claim:

1. An intervertebral implant, comprising:

a) a central body having a longitudinal axis, a proximal endportion and a distal endportion, wherein the proximal endportion is offset from the distal endportion in a proximal direction,

b) a first leg pivotally attached to the proximal endportion, wherein the first leg has a first orientation substantially in-line with the longitudinal axis of the central body to provide a footprint of the implant,

wherein the first leg is pivotable from the first orientation to a second orientation that is substantially perpendicular to the longitudinal axis of the central body,

wherein the second orientation changes the footprint of the implant,

wherein the first leg defines an external concave surface and an external convex surface opposite the concave surface, and the concave surface faces a distal direction in the second orientation, the distal direction opposite the proximal direction, and an entirety of the convex surface translates as the first leg pivots from the first orientation to the second orientation, and

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wherein when the first leg is in the second orientation, a proximal-most surface of the first leg is offset from the central body in the proximal direction.

2. The implant of claim 1, wherein the longitudinal axis of the central body is a curvilinear longitudinal axis.

3. The implant of claim 1, wherein the leg contacts an adjacent vertebral body.

4. The implant of claim 1, wherein the central body has an intermediate portion comprising a convex sidewall and a concave sidewall, wherein the convex sidewall is substantially parallel to the concave sidewall.

5. The implant of claim 1, wherein the first leg constitutes an upper surface of the implant.

6. A method of inserting the intervertebral implant of claim 1 into a disc space, comprising the steps of:

- a) attaching an inserter to the first leg of the intervertebral implant,
- b) after the attaching step, inserting the intervertebral implant into the disc space using the inserter,
- c) pivoting the first leg of the inserted implant.

7. The method of claim 6, wherein the inserting step includes initially inserting the implant so that the longitudinal axis of the central body has a substantially anterior-posterior orientation in the disc space.

8. The method of claim 7, wherein the inserting step comprises causing the longitudinal axis of the central body to have a substantially lateral orientation in the disc space.

9. The method of claim 8, wherein the first leg resides substantially anterior to the central body after step c).

10. The method of claim 9, wherein the leg contacts a vertebral body adjacent the disc space.

11. The method of claim 6, wherein the pivoting step comprises pivoting the first leg from the first orientation to the second orientation.

12. The method of claim 6, wherein the central body has an intermediate portion comprising a convex sidewall and a concave sidewall, wherein the convex sidewall is substantially parallel to and anterior to the concave sidewall.

13. The intervertebral implant of claim 1, wherein the central body defines a body width along a direction perpendicular to the longitudinal axis, the first leg defines a leg width along the direction perpendicular to the longitudinal axis, and in the first orientation the leg width is less than the body width.

14. A system comprising:
the intervertebral implant of claim 1; and
a pedicle screw.

15. An intervertebral implant, comprising:

- a) a central body having a longitudinal axis, a proximal endportion and a distal endportion, wherein the central body defines a central body width along a direction perpendicular to the longitudinal axis,
- b) a first leg pivotally attached to the proximal endportion, wherein the first leg has an external concave face and an external convex face opposite the concave face and spaced from the concave face along a central leg axis of the first leg,

wherein the first leg is pivotable between a first orientation whereby the central leg axis is angularly offset from the longitudinal axis, and a second orientation whereby the central leg axis extends substantially in a common direction as the longitudinal axis, and wherein the first leg defines a distance from the concave face to the convex face along the central leg axis, the distance less than the central body width.

16. The implant of claim 15, wherein the longitudinal axis of the central body is a curvilinear longitudinal axis.

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17. The implant of claim 15, wherein the leg is configured to contact an adjacent vertebral body.

18. The implant of claim 15, wherein the central body has an intermediate portion comprising a convex sidewall and a concave sidewall, wherein the convex sidewall is substantially parallel to the concave sidewall.

19. The implant of claim 15, wherein the first leg constitutes an upper surface of the implant.

20. The intervertebral implant of claim 15, wherein the first leg defines a leg width along the direction perpendicular to the longitudinal axis, and the leg width is less than the body width when the first leg is in the first orientation.

21. A system comprising:
the intervertebral implant of claim 15; and
a pedicle screw.

22. The intervertebral implant of claim 15, wherein the central leg axis is substantially perpendicular to the longitudinal axis when the first leg is in the first orientation.

23. An assembly intervertebral implant comprising:

- a) a central body having endplates spaced from each other along a transverse direction, a longitudinal axis and proximal and distal endportions spaced from each other along the longitudinal axis, wherein the central body has a body width along a direction perpendicular to both the longitudinal axis and the transverse direction, and

- b) a first leg pivotally attached to the proximal endportion, the first leg having an external concave surface and an external convex surface opposite the concave surface, wherein the first leg has a first orientation substantially in-line with the longitudinal axis of the central body to provide a first implant footprint,

wherein the first leg is pivotable between the first orientation and a second orientation, whereby the first leg is angularly offset with respect to the longitudinal axis of the central body so as to produce a second implant footprint that is different than the first implant footprint, and

wherein when the leg is in the first orientation, 1) the first leg has a leg width along the direction perpendicular to both the longitudinal axis and the transverse direction, and 2) the leg width along an entirety of the first leg is less than the body width along an entirety of the central body.

24. The implant of claim 23, wherein the longitudinal axis of the central body is a curvilinear longitudinal axis.

25. The implant of claim 23, wherein the leg contacts an adjacent vertebral body.

26. The assembly of claim 23, wherein the distal endportion is offset from the proximal endportion in a distal direction, and the concave surface faces the distal direction in the second orientation.

27. The intervertebral implant of claim 23, wherein the first leg defines a first leg distance from the concave surface to the convex surface, and the first leg distance is less than the body width.

28. The intervertebral implant of claim 23, wherein the proximal endportion is spaced from the distal endportion in a proximal direction, and when the first leg is in the second orientation, a proximal-most surface of the first leg is offset from the central body in the proximal direction.

29. The intervertebral implant of claim 28, wherein the convex surface is spaced from the concave surface in the proximal direction when the first leg is in the second orientation.

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30. A system comprising:
the intervertebral implant of claim **23**; and
a pedicle screw.

31. The system as recited in claim **30**, further comprising
an inserter configured to be attached to the first leg of the
intervertebral implant. 5

32. A system comprising:
the intervertebral implant of claim **23**; and
an inserter configured to be attached to the first leg of the
intervertebral implant. 10

33. An intervertebral implant for insertion between upper
and lower vertebral endplates, comprising:

a) a central body having opposed endplates spaced from
each other along a transverse direction and configured
to face the upper and lower vertebral endplates, respec- 15
tively, the central body elongate along a longitudinal
body axis, and the central body defining a proximal
endportion and a distal endportion, and

b) a first leg pivotally attached to the proximal endportion, 20
the first leg having an external concave surface and an
external convex surface opposite the concave surface
along a central leg axis of the first leg,

wherein the first leg has a first orientation whereby the
central leg axis is substantially in-line with the longi- 25
tudinal axis of the central body to provide a first
footprint of the implant, and

wherein the first leg is pivotable to define a second
orientation whereby the central leg axis is angularly
offset with respect to the longitudinal axis of the central
body to provide a second footprint of the implant that 30
is different than the first footprint, and

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wherein the first leg is configured to define a position with
respect to the central body between the first orientation
and the second orientation such that a plane that
extends along both the longitudinal body axis and the
transverse direction passes through each of the concave
and convex surfaces.

34. The intervertebral implant of claim **33**, wherein the
convex surface is offset with respect to the concave surface
along the longitudinal body axis when the first leg is in the
second orientation. 10

35. The intervertebral implant of claim **33**, wherein the
central body defines a body width measured along a direc-
tion perpendicular to the longitudinal body axis, and the first
leg defines a leg width measured along the direction per-
pendicular to the longitudinal body-axis that is less than the 15
body width when the first leg is in the first orientation.

36. The intervertebral implant of claim **35**, wherein when
the first leg is in the second orientation, 1) the convex
surface is offset from the concave surface in a proximal
direction, and 2) a proximal-most surface of the first leg is
offset from the central body in the proximal direction. 20

37. The intervertebral implant as recited in claim **36**,
wherein the concave and convex surfaces are spaced from
each other a distance that is less than the body width.

38. A system comprising:
the intervertebral implant of claim **36**; and
a pedicle screw. 25

39. A system comprising:
the intervertebral implant of claim **33**; and
a pedicle screw. 30

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